DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 15, 2014

Renovis Surgical Technologies, Incorporated
% Sharyn Orton, Ph.D.
Senior Consultant
MEDIcept, Incorporated
200 Homer Avenue
Ashland, Massachusetts 01721

Re: K142095
Trade/Device Name: Renovis S134 Anterior Lumbar Interbody Fusion (ALIF) System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: OVD, MAX
Dated: September 15, 2014
Received: September 16, 2014

Dear Dr. Orton:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Ronald P. Jean -S for

Mark N. Melkerson
Director,
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142095

Device Name
Renovis S134 Anterior Lumbar Interbody Fusion (ALIF) System

Indications for Use *(Describe)*

The Renovis Lumbar Interbody Fusion (LIF) System is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) of the lumbar spine at one or two contiguous levels from L2-S1. Degenerative disc disease is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These DDD patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). Renovis LIF System implants are to be used with autogenous bone graft. Patients should be skeletally mature and have at least six months of non-operative treatment.

The Renovis S128 ALIF System is a stand-alone device and is intended to be used with the cover plate and screws provided and requires no additional supplementary fixation. The anterior cover plate must be utilized whenever the device is implanted using the bone screws provided. Should the physician choose to use fewer than the four screws provided, additional supplemental fixation cleared by the FDA for use in the lumbar spine must be used.

The Renovis S134 ALIF System must be used with supplemental fixation cleared by the FDA for use in the lumbar spine.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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RENOVIS

Special 510(k) Summary
as required by 21 CFR 807.92(a)
K142095

A) Submitted by: Renovis Surgical Technologies, Inc.
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Redlands, CA 92374
Phone: 909-557-2360
Fax: 909-307-8571

Official Contact: Anthony DeBenedictis
Vice President of Quality Assurance

Consultant: Sharyn Orton, Ph.D.
MEDIcept, Inc.
200 Homer Ave
Ashland, MA 01721

Date: October 14, 2014

B) Device Name: Intervertebral Fusion Device With Bone Graft, Lumbar

Common Name: Intervertebral body fusion device

Proprietary Name: S134 Anterior Lumbar Interbody Fusion (ALIF) System

Device Class: Class II – 888.3080

Regulation and and product codes: 21 CFR 888.3080
OVD – Intervertebral Body Fusion Device with Integrated Fixation, Lumbar
MAX - Intervertebral Body Fusion Device with Bone Graft, Lumbar

Classification panel: Orthopedic

C) Predicate:

- K140106 Renovis S128 Anterior Lumbar Interbody Fusion (ALIF) System

D) Device Description:

The purpose of this submission is an additional offering to the Renovis lumbar interbody fusion system portfolio. The S134 Anterior Lumbar Interbody Fusion (ALIF) System implants (cages) are intervertebral body fusion devices with a screw-less design that requires supplemental fixation. The S134 ALIF cages are available in a variety of sizes (widths, height, depths, and bone screw sizes) to suit the individual pathology and anatomical conditions of the patient. The implants are manufactured from PEEK or additively manufactured and machined Titanium. The PEEK markers are manufactured from Tantalum.

The Renovis S134 ALIF System cages are to be used with supplemental fixation, and are intended to be used with autogenous bone graft.

The Renovis S134 ALIF System is used with device specific instruments including trials.

The Renovis S134 ALIF System implants comply with the following material standards:

- ASTM F2026-08 Standard Specification for PEEK Polymers for Surgical Implant Applications
- ASTM F136-13 Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications
- ASTM F560-08, Standard Specification for Unalloyed Tantalum for Surgical Implant Applications

The S134 ALIF implants are provided gamma sterilized, and non-sterile (requiring sterilization by the end user).

E) Indications For Use:

The Renovis Lumbar Interbody Fusion (LIF) System is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) of the lumbar spine at one or two contiguous levels from L2-S1. Degenerative disc disease is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These DDD patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). Renovis LIF System implants are to be used with autogenous bone graft. Patients should be skeletally mature and have at least six months of non-operative treatment.

The Renovis S128 ALIF System is a stand-alone device and is intended to be used with the cover plate and screws provided and requires no additional supplementary fixation. The anterior cover plate must be utilized whenever the device is implanted using the bone screws provided. Should the physician choose to use fewer than the four screws provided, additional supplemental fixation cleared by the FDA for use in the lumbar spine must be used.

The Renovis S134 ALIF System must be used with supplemental fixation cleared by the FDA for use in the lumbar spine.

F) Substantial Equivalence Comparison and Discussion

Comparison of technological characteristics, engineering rationale and FEA were used to determine that this design change does not introduce a new worst case.

Conclusion

The Renovis S134 ALIF System implants have the same footprint (ID and OD profile dimensions), materials, manufacturing methods, and sterilization offerings; and similar intended use, design and function as the Renovis S128 ALIF System implant. Therefore, the Renovis S134 ALIF System is substantially equivalent to the predicate device.

G) Compliance with Design Controls

The results of assessment under Design Controls support that the Renovis S134 ALIF System is substantially equivalent to the predicate device. The offering of implants that are not standalone and require supplemental fixation does not raise new issues of safety or effectiveness.

H) Compliance with Consensus Standards and FDA Guidance

The Renovis S134 ALIF System complies with:

- ASTM F136-13 Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401)
- ASTM F2026-12 Standard Specification for Polyetheretherketone (PEEK) Polymers for Surgical Implant Applications
- ASTM F560-08 Standard Specification for Unalloyed Tantalum for Surgical Implant Applications (UNS R05200, UNS R05400)
- ASTM F983-86 (Reapproved 2013) Standard Practice for Permanent Marking of Orthopaedic Implant Components
- ASTM F565-04 (Reapproved 2013) Standard Practice for Care and Handling of Orthopedic Implants and Instruments
- Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Intervertebral Body Fusion Device, October 2007